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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 18

mailed 11/15/99

Application Number: 08/501743
Filing Date: 07/12/95
Appellant(s): FAHIM ET AL

Michael I. Stewart
For Appellant

EXAMINER'S ANSWER

This is in response to appellant's brief on appeal filed August 31, 1999.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

Appellant's brief includes a statement that claims 27-39 and 42 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

The following is a listing of the prior art of record relied upon in the rejection of claims under appeal.

Englund et al, "Controlled Study of a New Five-Component Acellular Pertussis Vaccine in Adults and Young Children" Journal of Infectious Diseases, Vol. 166 (1992), pp. 1436-1441.

(10) Grounds of Rejection

The following grounds of rejection are applicable to the appealed claims:

Claims 27-29, 31-34, 38, 39 and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Englund et al.

Englund et al discloses an acellular pertussis vaccine used in a controlled study in adults and young children (abstract). Englund et al discloses a new five-component acellular pertussis (AP) vaccine containing 10 micrograms of pertussis toxoid, 5 micrograms of filamentous hemagglutinin, 5 micrograms of combined agglutinogen 2 and 3, and 3 micrograms of pertactin (abstract; materials and methods, pp 1436-1437). These are purified antigens (p. 1436). Pertussis or whooping cough is caused by *Bordetella pertussis*. Englund et al discloses the use of an adjuvant, aluminum phosphate in the vaccine composition. This vaccine is identical to that claimed by Applicants, is highly effective and is used in a method of immunizing a human host against pertussis. The prior art of Englund et al anticipates the claimed invention.

Claims 27-39 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Englund et al.

Englund et al teaches an acellular pertussis vaccine used in a controlled study in adults and young children (abstract). Englund et al teaches a new five-component acellular pertussis (AP) vaccine containing 10 micrograms of pertussis toxoid, 5 micrograms of filamentous hemagglutinin, 5 micrograms of combined agglutinogen 2 and 3, and 3 micrograms of pertactin (abstract; materials and methods, pp 1436-1437). These are purified antigens (p. 1436). Pertussis or whooping cough is caused by *Bordetella pertussis*. Englund et al

teaches the use of an adjuvant, aluminum phosphate in the vaccine composition. Englund et al teaches a vaccine composition comprising the five-component acellular pertussis (AP) and further comprising tetanus toxoid (15 Lfs) and diphtheria toxoid (5 Lfs) (materials and methods, 1437, col. 1) as set forth in the claims. The prior art teaches a method of immunizing a human host against pertussis. The prior art teaches the claimed invention except for the specific amounts of all purified components or ratios as set forth in Applicants' claims. However, it would have been obvious to a person of ordinary skill in the art at the time the invention was made that the vaccines of Englund et al either contained the component concentrations claimed by Applicants based on the ordinary level of skill in the art.

(11) Response to Argument

Applicants have asserted that although the components of the vaccine formulation are disclosed by Englund et al, there is no indication that such formulation may be used to achieve an efficacy level of at least about 70% in an at-risk population. However, this is a product claim, vaccine, and as stated the prior art vaccine appears to be consistent with the various characteristics inherent to the vaccine as claimed. This is an inherent property or characteristic. Since the Office does not have the facilities for examining and comparing applicants' vaccine and efficacy level with the vaccine and efficacy level of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the vaccine of the prior art does not possess the same material structural and functional characteristics of the claimed vaccine). See In re Best, 562 F2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicants have asserted that the prior art is lacking with regard to any manner of predicting the efficacy of such a composition in the absence of large scale clinical trail among an at-risk population. The prior art teaches the use of the vaccine in large scale trails as set forth in the methods and materials by using adults/children and in the results (pp. 1436-1439).

Applicants have asserted that the prior art does not disclose the limitations of extent of protection of at least about 70%, 80% or 85% for a case of various durations of spasmodic coughing and bacterial infection. However, this is a product claim, vaccine, and as stated the prior art vaccine appears to be consistent with the various characteristics inherent to the vaccine as claimed. This is an inherent property or characteristic. Since the Office does not have the facilities for examining and comparing applicants' vaccine and efficacy level with the vaccine and efficacy level of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the vaccine of the prior art does not possess the same material structural and functional characteristics of the claimed vaccine). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicants have asserted that the prior art is defective with regard to the level of efficacy for the claimed agglutinogen and with regard to the level of efficacy for the claimed formulation with alum as an adjuvant. However, this is a product claim, vaccine, and as stated the prior art vaccine appears to be consistent with the various characteristics inherent to the vaccine as claimed. This is an inherent property or characteristic. Since the Office does not have the facilities for examining and comparing applicants' vaccine and efficacy level with the vaccine and efficacy level of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the vaccine of the prior art does not possess the same material structural and functional characteristics of the claimed vaccine). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Because references are presumed to be operable, a patentee (or applicant) has the burden of proving that no operable technique existed for producing the structure disclosed therein. Freeman v. Minnesota Mining & Mfg. Co. (DC Del 1988) 693 FSupp. 134, 9 PQ2d 1111. A clear albeit accidental, disclosure can anticipate a claimed composition containing

ingredients in specified ratios, even though the author of the disclosure did not know the scientific explanation of his disclosure. General Electric Co. V. Watson, Comr. Pats. (DCDC 1960) 188 FSupp. 341, 127 USPQ 326. The specific description of a chemical compound or its formula in the prior art is anticipation of any claim to that compound even if the reference discloses no method for its production. References are presumed enabling and the burden is on applicant to prove they are not. In re Collins (CCPA 1972) 462 F2d 538, 174 USPQ 333. If the chemical composition of the claimed article of manufacture recited in the claims is the same as the identical structure of the prior art, it is immaterial that the applicant recognized different advantages flowing therefrom than did the prior art Ex parte Tummers et al. (POBA 1962) 137 USPQ 444, or that the claim thereto recites a property thereof not disclosed in the prior art, Titanium Metals Corp. Of America v. Banner (CAFC 1985) 778 F2d 775, 227 USPQ 775; In re Spada (CAFC 1990) 911 F2d 705, 15 PQ2d 1655. A patent applicant is free to recite features of an apparatus either structurally or functionally. See In re Swinehart, 439 F.2d 210, 212, 169 USPQ 226, 228 (CCPA 1971) (" [T]here is nothing intrinsically wrong with [defining something by what it does rather than what it is] in drafting patent claims."). Yet, choosing to define an element functionally, i.e., by what it does, carries with it a risk. As our predecessor court stated in Swinehart, 439 F.2d at 213, 169 USPQ at 228: where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, it possesses the authority to require the applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on.

It is noted that claims 36 and 37 were not rejected under 102(b) as being anticipated by Englund et al. However, Englund et al discloses a vaccine comprising pertussis toxoid, filamentous hemagglutinin, combined agglutinogen 2 and 3, pertactin and further comprising tetanus toxoid (5 Lfs) and diphtheria (15 Lfs) (materials and methods, p. 1437, col. 1).

In an effort to provide compact and expedited prosecution, and avoid filing of a third Appeal Brief this rejection has not been set forth. However, these claims, 36 and 37, have been rejected under 35 U.S.C. 103(a) as being unpatentable over Englund et al.

With regard to the 103 obviousness rejection, Applicants have asserted that the recitation of the specific proportions or ratios of these components (claims 30 and 35) are neither disclosed or suggested by the prior art and that the this contribution is not a "mere discovery" but rather the finding that, by formulating the composition in specific proportions, an unexpected result is achieved, namely an efficacy of at least 70% among an at-risk population. However, to determine optimum concentrations of reactants is within the level of ordinary skill in the art. See In re Kronig, 190 USPQ 425. It would have been obvious to one having ordinary skill in the art at the time the invention was made to determine the amount of the purified antigen(s) and their ratios, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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November 4, 1999

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